DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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October 7, 2014

Pihsiang Machinery Mfg. Co., Ltd
c/o Dave Yungvirt
Third Party Review Group, LLC (TPRG)
45 Rockefellar Plaza, Suite 2000
New York, NY 10111

Re: K142027
Trade/Device Name: 888 WNLE Powered Wheelchair/ROVI X3
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: September 21, 2014
Received: September 25, 2014

Dear Mr. Yungvirt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142027

Device Name
888 WNLE Powered Wheelchair/ROVI X3

Indications for Use *(Describe)*
The intended use of the 888 WNLE powered wheelchair by Pihsiang Machinery Mfg. Co., LTD is to provide mobility solutions to individuals who are limited to a seated position.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
888 WNLE
Power Wheelchair

Submitter's Name & Address:

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Official Correspondent

Name: David Lin
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Email: dlin@shoprider.com
Phone: 310-328-8866 Ext. 102
Fax: 310-328-8185

Date Prepared:

September 22nd, 2014

Name of Device and Proprietary Name:

Pihsiang Machinery Mfg. Co. LTD Model: 888 WNLE Powered Wheelchair
Shoprider Mobility Products, Inc. Marketed name: Rovi X3

Common or Usual Name:

Powered Wheelchair

Classification Name:

Wheelchair, Powered, **Class II, 21 CFR 890.3860**

Product Code:

ITI

Indications for Use:

The intended use of the 888 WNLE powered wheelchair by Pihsiang Machinery Mfg. Co., LTD is to provide mobility solutions to individuals who are limited to a seated position.

Device Description:

The 888 WNLE is a Center-wheel Drive Powered Wheelchair with front and rear pivoting caster wheels. It is equipped with a pair of electronic 4 pole 24vdc motors, electronic solenoid brakes, and two 12V 60Ah Group M34 batteries. The 888 WNLE is controlled by a PG Drives VR2 controller and is configured for an Off-board Charger. The 888 WNLE has front and rear battery access, and the main frame is composed of a welded steel construction. The 888 WNLE is joystick controlled, which when deflected, informs the controller to release the electromagnetic parking brake and apply power to the motors. This enables the chair to travel in the direction selected by the user with the joystick. When the user releases the joystick, the controller employs regenerative braking to bring the chair to a stop before electromagnetic parking brakes are applied automatically. The 888 WNLE is intended to be driven on various dry outdoor surfaces such as blacktop, concrete, and asphalt.

The 888 WNLE is also equipped with a vinyl Captain's seat with adjustable reclining back. Optional accessories are adjustable height armrests and a center mount foot platform, which help to properly position and support the user.

Predicate Device:

Jazzy 600 (K042612)

Predicate Device Indications for Use:

The intended use of the Pride Mobility Products Corp. Jazzy 600 Powered Wheelchair is to provide mobility to persons limited to a seated position.

Comparison to Predicate Devices:

The 888 WNLE is substantially equivalent to the Pride Mobility Jazzy 600 (K042612) when comparing performance, maneuverability, stability, and dimensions. Both the 888 WNLE and Jazzy 600 (K042612) utilize a center mounted drive wheel with front and rear casters (on the ground) to maintain stability. The 888 WNLE is equipped with a suspension that allows the unit to achieve the same Intended use of the Jazzy 600, providing mobility to persons limited to a seated position, while maintaining optimal stability and without hindering performance. Both the 888 WNLE and the Jazzy 600 (K042612) utilize side mounted freewheel levers, and are equipped with PG Drives VR2 motor control systems.
The technical differences that exist between the 888 WNLE and the Jazzy 600 (K042612) are few. While the 888 WNLE is equipped with a larger capacity battery 60Ah 12vdc (Group M34), it is the same type of energy source utilized in the Jazzy 600 (K042612), 55Ah 12Vdc battery (Group NF22). Another difference is that the 888 WNLE is designed for front and rear battery access while the Jazzy 600 (K042612) is designed for front battery access only. Finally the **888** WNLE is equipped with two 4 pole 24vdc motors while the Jazzy 600 (K042612) is equipped with two 2 pole 24vdc motors. The addition of the

extra 2 poles to the drive motor provide for extra power and enables the 888 WNLE to provide the necessary performance to fulfill its intended use.

Non-Clinical Testing:

RESNA WC Vol.1 2009 - Requirements and Test Methods for Wheelchairs (Including Scooters)

Section 1: Determination of Static Stability
Section 5: Determination of dimensions, mass, and maneuvering space
Section 7: Method of measurement of seating and wheel dimensions
Section 8: Requirements and test methods for static, impact and fatigue strengths
Section 11: Test Dummies
Section 13: Determination of coefficient of friction of test surfaces
Section 15: Requirements for information disclosure, documentation and labeling
Section 16: Resistance to Ignition of Upholstered Parts – Requirements and Test Methods
Section 22: Set-up procedures
Section 26: Vocabulary

RESNA WC Vol. 2 2009 - Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems

Section 2: Determination of dynamic stability of electrically powered wheelchairs
Section 3: Determination of effectiveness of brakes
Section 4: Energy consumption of electrically powered wheelchairs and scooters for determination of theoretical distance range
Section 6: Determination of maximum speed, acceleration and deceleration of electrically powered wheelchairs
Section 9: Climatic tests for electrically powered wheelchairs
Section 10: Determination of obstacle –climbing ability of electrically powered wheelchairs
Section 14: Power and control systems for electrically powered wheelchairs – requirements and test methods
Section 21: Requirements and Test Methods for Electromagnetic Compatibility of electrically powered wheelchairs and motorized scooters

ISO 14971: 2009 Medical devices -- Application of risk management to medical devices

Compliance to ISO 10993 Biocompatibility

Summary of Excluded Section:

Certain sections of RESNA WC-1/-2: 2009 were not evaluated because they were specific to features not available or applicable to 888 WNLE. The subsections are detailed in FDA-3654 Standards and Data Report forms.

Conclusion of Non-Clinical Testing:
The 888 WNLE has been tested to evaluate its safety and performance. The 888 WNLE was found to be in compliance with all voluntary test standards referenced above. Performance testing indicates the 888 WNLE is capable of negotiating obstacles up to 80mm in height, is proven to be stable on inclines up to 9º, and capable of theoretical range of 16.4 miles. These results were obtained using the maximum capacity of 300 lbs. These results are well above the requirements of 60mm obstacle height, 7.5º for inclines, and 12 miles for theoretical range. Additional testing has also proven the 888 WNLE is structurally sound, compliant to all electrical, and flammability standards. Biocompatibility for polyurethane vinyl (seat) and polyurethane foam (armrests) has previously been evaluated and cleared under ITI powered wheelchair TE 888W (K983808). Exclusions to the voluntary standards listed above are detailed in FDA-3654 Standards and Data Reports.

Discussion of Clinical Testing Performed:
N/A

Conclusions:
The 888 WNLE has an equivalent intended use and similar technological characteristics as the Jazzy 600 (K042612). The results of non-clinical testing and the comparison of the 888 WNLE to the Jazzy 600 (K042612) have proven that the technical differences do not raise any new questions of safety or effectiveness. Based on these findings, it is the assertion that the 888 WNLE is substantially equivalent to the Pride Mobility Jazzy 600 (K042612) and is safe for the Intended Use.